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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/079,043	02/20/2002	Markus Kostrzewa	B0032/7019	5152
21127	7590	10/19/2004	EXAMINER	
KUDIRKA & JOBSE, LLP ONE STATE STREET SUITE 800 BOSTON, MA 02109			HORLICK, KENNETH R	
			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/079,043	KOSTRZEWA ET AL.	
	Examiner	Art Unit	
	Kenneth R Horlick	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koster et al. (US 6,221,601) in view of either of Koster (US 5,547,835) or Monforte et al. (US 5,830,655).

These claims are drawn to methods comprising: providing an extension primer having a nucleotide chain that contains a photocleavable linker and attaching the primer to DNA adjacent to a mutation site; extending the primer using mutation dependent primer extension; cleaving the photocleavable linker with UV light irradiation to produce a DNA cleavage product; and analyzing the DNA cleavage product using mass spectrometric analysis.

Koster et al. disclose a method comprising: providing an extension primer having a nucleotide chain that contains a cleavable linker and attaching the primer to DNA adjacent to a mutation site; extending the primer using mutation dependent primer extension; cleaving the cleavable linker to produce a DNA cleavage product; and analyzing the DNA cleavage product using mass spectrometric analysis. See column 4, line 55 to column 5, line 9; Example 7 in columns 27-30; claim 1 in column 59.

Koster et al. do not disclose the use of a primer specifically having a photocleavable linker.

Koster discloses the use of a primer having a photocleavable linker in the analysis of DNA extension reactions via mass spectroscopic means (see column 11, line 52 to column 12, line 10; claims 5-9).

Monforte et al. also disclose the use of a primer having a photocleavable linker in the analysis of DNA extension reactions via mass spectroscopic means (see abstract; columns 4-10, column 13, lines 40-46; column 38, lines 42-49). This patent further discloses the use of a nitrobenzyl group as a photocleavable linkage.

One of ordinary skill in the art would have been motivated to use a primer having a photocleavable portion in the method of Koster et al. because both Koster and Monforte et al. disclosed the advantageous use of such a primer in the analysis of DNA extension products by mass spectrometry. It is to be noted that the use of the advantageous primer in each of Koster and Monforte et al. is in the same context as in the method of the primary reference Koster et al. (analysis of DNA extension products

by mass spectroscopy). Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to carry out the claimed methods.

2. With respect to the above rejection, the arguments of the response filed 07/23/04 have been fully considered, but are not found persuasive. Despite the attempt of the response to show differences in the goals or "intended use" of the disclosed method versus that in the cited references, it is maintained that the noted combined teachings of the references is suggestive of what is being claimed. For example, claim 1 has been amended with the limitation "the primer extension using at least one chain terminator that terminates the extension at one of a plurality of predetermined lengths". The language "that terminates...", however, relates to an intended use of the chain terminator rather than to a method step which can be given patentable weight. The '601 patent clearly discloses a method in which primer extension using at least one chain terminator terminates extension at a predetermined length; thus, this new limitation does not distinguish the claims from what is taught by Koster et al. Also, the amendment to claim 1 of analyzing the DNA cleavage product "to determine the nucleotide present at the mutation site" does not distinguish over Koster et al., as the goal of the embodiment cited in the rejection is to determine the identity of a mutation.

In summary, it is submitted that the arguments in the response are mainly directed to teachings in the references which are not being relied upon in the rejection, or do not appear to correspond to actual limitation(s) in the claims. Thus, it is maintained that the '601 patent discloses all the limitations of the claims except for a

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primer having a photocleavable linker, and that both the secondary references ('835 and '655 patents) disclose the use and advantages of such a primer with a photocleavable linker in a similar context, and that the combined references support a proper case of prima facie obviousness.

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


4. No claims are free of the prior art.

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5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth R Horlick whose telephone number is 571-272-0784. The examiner can normally be reached on Monday-Thursday 6:30AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Kenneth R Horlick
Primary Examiner
Art Unit 1637

10/12/04